



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3284-N]

Medicare Program; Revised Process for Making National Coverage Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice updates the process we use for opening, deciding or reconsidering national coverage determinations (NCDs) under the Social Security Act (the Act). It addresses external requests and internal reviews for new NCDs or for reconsideration of existing NCDs. The notice further outlines an expedited administrative process to remove certain NCDs, thereby enabling local Medicare contractors to determine coverage under the Act. This notice does not alter or amend our regulations that establish rules related to the administrative review of NCDs.

DATES: This notice is effective on [OFR—insert the date of publication in the **Federal Register**.]

FOR FURTHER INFORMATION CONTACT:

Katherine Tillman, (410)786-9252.

SUPPLEMENTARY INFORMATION:

I. Background

In a September 26, 2003, **Federal Register** notice (68 FR 55634), we announced our procedures for considering national coverage determination (NCD) requests and our procedure for issuing NCDs, including the role of external public requests to open an NCD and our procedures for internally-generated NCD reviews. As we strive to continually improve our processes and in recognition of the changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, enacted on December 8, 2003), we are superseding the 2003 **Federal Register** notice with this updated notice.

II. Provisions of the Notice

This notice establishes the procedures for requesting an NCD or reconsideration of an existing NCD. We also describe how the public may participate in the NCD process during the indicated comment period(s). The topics addressed in the notice include the following:

- Informal contacts and inquiries prior to requesting a national coverage determination.
- What constitutes a complete, formal request for an NCD or formal request for reconsideration of an existing NCD.

- External requests for NCDs, including the following:

- ++ Request by an external party for a new NCD.

- ++ Request by an external party for reconsideration of an existing NCD.

- ++ Request by an aggrieved party (as defined below) to issue an NCD when no NCD exists.

- CMS internally-generated review of NCDs, including the following:

- ++ CMS internal review for a new NCD.

- ++ CMS internal review for reconsideration of an existing NCD.

- An expedited process to remove NCDs under certain circumstances.

Based on our experience since 2003 with the current NCD process, we are establishing a new procedure to be used in circumstances in which we have previously issued an NCD, but have now determined that the NCD is no longer needed. Since we would not be establishing a new NCD, we would use an expedited process to remove these NCDs. After the effective date of the removal of the NCD, local Medicare contractors would determine coverage under section 1862(a)(1) of the Act for those specific items or services previously addressed through the NCD. We describe this process and the opportunity for public participation in this process in section IV.C of this notice.

We are also restating our process for developing an NCD to provide clarity and transparency for the public pertaining to modifications made to the coverage process since the MMA. As in the 2003 **Federal Register** notice, we will inform the public by addressing the following in this notice:

- The internal and external processes for requesting an NCD or an NCD reconsideration.
- A tracking system that provides public notice of our acceptance of a complete, formal request and subsequent actions in a web-based format.
- The process we use to afford notice and opportunity for public comment before issuing a decision memorandum.
- How we use public comments to inform the NCD final decision.

We continue to pursue our efforts to work with various sectors of the scientific and medical community to develop and publish on our website documents that describe our approach when analyzing scientific and clinical evidence to develop an NCD. The CMS coverage website can be accessed at <http://www.cms.gov/Medicare/Coverage/CoverageGenInfo/index.html>.

III. Medicare Coverage – General Principles

A. Statutory Authority

The Medicare program was established by Title XVIII of the Act. Part A is the hospital insurance program and Part B is the voluntary supplementary medical insurance program. The scope of benefits available to eligible beneficiaries under Part A and Part B is prescribed by law in sections 1812 and 1832 of the Act. Part C, known as the Medicare Advantage Program, includes at a minimum, all of the items and services available under Part A and Part B to individuals enrolled in the plan. On January 1, 2006, Medicare began to cover prescription drugs through a new voluntary and privately-administered Part D program, established by the MMA. To obtain prescription drug coverage, Medicare beneficiaries must take the affirmative step of

enrolling in a private Medicare Part D plan that is either a stand-alone prescription drug plan (PDP) or a Medicare Advantage prescription drug plan (MA-PD).

In addition, with relatively few exceptions, the statute provides in section 1862(a)(1) of the Act that no payment may be made under Part A or Part B for any expenses incurred for items or services which “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” The Supreme Court has recognized that “[t]he Secretary's decision as to whether a particular medical service is ‘reasonable and necessary’ and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions.” Heckler v. Ringer, 466 U.S. 602, 617 (1984).

This notice concerns our procedures for making NCDs for items and services under Part A or Part B. NCDs serve as generally applicable rules to ensure that similar claims for items or services are covered in the same manner. Often an NCD is written in terms of defined clinical characteristics that identify a population that may or may not receive Medicare coverage for a particular item or service. The term “national coverage determination” is defined by statute and means a determination by the Secretary of the Department of Health and Human Services (Secretary) with respect to whether or not a particular item or service is covered nationally under Title XVIII of the Act. NCDs are controlling authorities for Medicare contractors and adjudicators as described more fully in 42 CFR 405.1060.

In the absence of an NCD, Medicare contractors may establish a local coverage determination (LCD) (defined in section 1869(f)(2)(B) of the Act) or adjudicate claims on a case-by-case basis. The case-by-case adjudicatory model permits consideration of a beneficiary’s particular factual circumstances described in the medical record. The case-by-case model affords more flexibility to consider a particular individual’s medical condition than is possible when the agency establishes a generally applicable rule.

B. Differences between Food and Drug Administration (FDA) and CMS Review

Parties interested in the coverage of a drug or device may contact us with an inquiry on Medicare coverage while the particular drug or device is proceeding through the Food and Drug Administration (FDA) review process. Since the FDA is charged with regulating whether devices or pharmaceuticals are safe and effective for their intended use by consumers, generally we will not accept a coverage request for a device or pharmaceutical that has not been approved or cleared for marketing by the FDA for at least one indication; one exception is Category B Investigational Device Exemption (IDE) devices. A Category B IDE device is a non-experimental/investigational device for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval or clearance for that device type.

Both CMS and FDA review scientific evidence and will likely review some of the same evidence to meet each agency's mission. Among other things, FDA reviews evidence to determine that a product is safe and effective, that is, it conducts a premarket review of products under a statutory standard and delegated authority (67 FR 66755) different from that of CMS. We also review clinical evidence to determine, among other things, whether the item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for the affected Medicare beneficiary population. An FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for consideration of Medicare coverage (except in specific circumstances). However, FDA approval or clearance alone does not entitle that technology to Medicare coverage.

IV. CMS' Process for Making a National Coverage Determination

Section 1862(l) of the Act establishes, among other things, a timeframe for the NCD

process and an opportunity for public comment on the agency's proposed decisions.

A. Informal Contacts and Inquiries before Requesting an NCD

We encourage, but do not require, potential requesters to communicate, via conference call or meeting, with our staff in the Coverage and Analysis Group (CAG) within the Center for Clinical Standards and Quality (CCSQ) before submission of a formal request. We have found that an initial submission of a "formal request" without any conversation with us generally requires additional clarification and discussion before we can definitively act on the request. A summary of the item or service and supporting documentation can be presented by the requester, and our staff can identify additional information that might be needed or helpful. Preliminary discussions are also the appropriate time for the requester to identify clinical trial protocols whose results will be later submitted to support an NCD request, if relevant. A positive response, however, to a clinical trial protocol is not an indication of forthcoming Medicare coverage.

A significant proportion of potential requesters have either withdrawn or substantially amended their initial requests after informal discussion with us. These instances have generally included one or more of the following factors:

- Existing coverage of the item or service is already available at the national or local level.
- The substance of the request concerns the coding or payment amount for the item or service and is therefore outside the scope of an NCD.
- The item or service falls outside the scope of the Medicare Part A and Part B benefits.
- The requester learns that the item or service, even if covered, would not be separately paid under the Medicare program, for example, the item or service would be included in a bundled payment.

- The requester recognizes the request would not be supported by a persuasive body of evidence.

Informal communications between us and the requester allow both parties to clarify the NCD request and discuss potential issues that would affect our review and implementation of coverage of the item or service, such as the issues discussed above. These meetings and conversations expedite consideration and ensure that the requester understands that all relevant materials must be submitted in a timely manner and not delay the opening of the NCD review.

B. What Constitutes a Complete, Formal Request for an NCD or a Complete, Formal Request for Reconsideration

We can initiate an NCD request or one can be initiated by an individual, (including a beneficiary), or an entity (including a medical professional society or business interest). We require that any request for an NCD review be a written “complete, formal request.” Acceptance of a complete, formal request indicates that we have sufficient information to conduct the NCD review. A request is considered to be a complete, formal request once the following conditions are met:

- The requester has provided a final letter of request that is not marked as a draft, and is clearly identified as “A Formal Request for a National Coverage Determination.” The requester must identify and submit the scientific evidence that he or she believes supports the request for coverage. Our review, however, is not limited to the materials submitted by the requester.

- Supporting documentation must include a full and complete description of the item or service in the request and scientific evidence supporting the clinical indications for the item or service. This includes a specific detailed description of the proposed use of the item or service, including the target Medicare population and the medical indication(s) for which it can be used and whether the item or service is intended for use by health care providers or beneficiaries.

- If the requester has submitted an application to the FDA for premarket approval or

510(k) clearance of the product for which coverage is sought, a copy of the “integrated summary of safety data” and “integrated summary of effectiveness data”, or the combined “summary of safety and effectiveness data” portions of the FDA application must be included. (Section 510(k) of the Food, Drug, and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance.)

- In the case of items or services that are eligible for a 510(k) clearance by the FDA, the request must include identification of the predicate devices to which the item or service is claimed to be substantially equivalent.

- The request must include information regarding the use of an item or service (for example, drug or device) subject to FDA regulation as well as the status of current FDA regulatory review of the item or service involved. An FDA regulated item or service would include the labeling submitted to FDA or approved by the FDA for that article, together with an indication of whether the article for which review is being requested is covered under the labeled indication(s). We recognize that the labeling on FDA-approved products sometimes changes. For purposes of our review, we are interested in the labeled indications at the time a requester submits a formal request. If during our review, the labeled indication or status of pending FDA approval or clearance changes, the requester must notify us of those changes.

- The request must state the Medicare Part A or Part B benefit category or categories in which the requester believes the item or service falls. Medicare does not develop NCDs to establish coverage of items or services that fall outside the scope of the Part A or Part B benefits.

- Requests for NCDs may be submitted electronically via the Coverage Center website using the “Contact Us” link at

<http://www.cms.gov/Medicare/Coverage/InfoExchange/contactus.html>.

Requests may also be submitted to the Centers for Medicare & Medicaid Services; Director, Coverage and Analysis Group; 7500 Security Blvd; Baltimore, MD 21244.

We will consider a request to be a complete, formal request if the following conditions are met:

- The request is in writing.
- The request clearly identifies the statutorily-defined benefit category to which the requester believes the item or service applies and contains enough information for us to make a benefit category determination.
- The request is accompanied by sufficient, supporting evidentiary documentation.
- The information provided addresses relevance, usefulness, or the medical benefits of the item or service to the Medicare population.
- The information fully explains the design, purpose, and method of using the item or service for which the request is made.

C. External Requests for National Coverage Determinations

1. Request by an External Party for a New National Coverage Determination

Typically, a requester is a Medicare beneficiary, a manufacturer, a physician or a physician professional association. A request may be to establish, limit, or entirely remove coverage.

Upon acceptance of a complete, formal request, publication of a tracking sheet on the CMS website enables interested individuals to participate in and monitor the progress of our review. The tracking sheet contains a reference number, the name of the issue under consideration, requests for public comments, and summarizes the significant actions we have taken. The tracking sheet is a key element in making our NCD process efficient, open, and accessible to the public.

A formal evidence review is then undertaken to determine whether or not an unbiased interpretation of the available evidence base supports or refutes the requested coverage in whole or in part. A proposed decision is normally issued for public comment within six months of

opening the NCD review. Consistent with section 1862(l)(3)(B) of the Act, we provide 30 days for public comment on the proposal. Not later than 60 days after the close of the 30-day public comment period, we issue a final NCD. The final NCD decision memorandum includes a summary of the public comments on the proposed decision as well as responses to those comments. The proposed and final memoranda also include the scientific basis for our coverage determination, for example, an analysis and summary of the evidence considered (including medical, technical, and scientific evidence). The statutory timeframes, however, vary depending on whether or not we commission a technology assessment from an outside entity, or whether we decide to convene the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) to discuss the quality of the evidence, or whether a clinical trial is requested.

2. Request by an External Party for Reconsideration of an Existing NCD

When an NCD currently exists, any individual or entity may request that we reconsider any provision of that NCD by filing a complete formal request for reconsideration. Similar to a request for a new NCD, the request for reconsideration must be submitted in writing and be clearly identified. We consider accepting a request to revise an existing NCD at any time, but only if the requester presents documentation that meets one of the following criteria:

- Additional scientific evidence that was not considered during the most recent review along with a sound premise by the requester that new evidence may change the NCD decision.
- Plausible arguments that our conclusion materially misinterpreted the existing evidence at the time the NCD was decided.

Similar to a request for a new NCD, we consider a reconsideration request to be a “complete, formal request” if the following conditions are met:

- The requester provides a final letter of request (for example, not marked as a “draft”), and clearly identifies the request as a “Formal Request for NCD Reconsideration.”
- The requester identifies the scientific evidence that he or she believes supports the

request for reconsideration (see above). Our review, however, is not limited to the materials submitted by the requester.

- The written request includes and supports any additional Medicare Part A or Part B benefit categories in which the requester believes the item or service falls.
- The request includes supporting documentation and is received electronically (unless there is good cause for only a hardcopy submission such as inability to scan necessary documents for electronic submission or lack of access to an electronic method of submission). Requests for NCDs may be submitted electronically via the Coverage Center website using the “Contact Us” link. Requests may also be submitted to the Centers for Medicare & Medicaid Services; Director, Coverage and Analysis Group; 7500 Security Blvd; Baltimore, MD 21244.

We review materials presented in a complete, formal request by the requester. We also review other related clinical materials before accepting a request for reconsideration. In a change from the 2003 **Federal Register** notice and because of the time required for clinical research, reviews and analysis in a global health arena, we have determined that 60 days is usually a reasonable time period for us to make a decision to accept or reject decline an external NCD reconsideration request. If we accept the request, we post the letter requesting reconsideration together with a tracking sheet announcing that a reconsideration of the NCD has begun. If we decline the request, we will send a letter to the requester, rejecting the reconsideration request.

3. Request by an Aggrieved Party to Issue a Coverage or Noncoverage NCD

Section 1869(f)(4) of the Act permits certain aggrieved persons to make a request that the Secretary issue a national coverage or noncoverage determination with respect to a particular type or class of items or services, if the Secretary has not made a national coverage or noncoverage determination. These individuals are described in section 1869(f) (5) of the Act as “individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need

of the item or service that is the subject of the coverage determination.” Thus, this option can be invoked only for an initial request if we have not issued a coverage or noncoverage NCD. In these rare instances related to requests made by aggrieved parties, the statute establishes specific time deadlines for our consideration of such requests and we will notify the public through the posting of the NCD Tracking sheet when this occurs.

D. Internally-Generated NCD Review

1. Internally-Generated Review of an NCD

We may internally initiate the NCD process. The following are examples of circumstances that may prompt us, when supported by our initial investigation of available evidence for review, to generate an internal NCD review on new or longstanding items or services:

- Practitioners, patients, or other members of the public have raised significant questions about the health outcomes attributable to the use of the items or services for the Medicare beneficiary population.
- New evidence or reasonable re-interpretation of previously available evidence indicates that a national coverage review may be warranted.
- Local coverage policies on a particular item or service may vary in language or implementation. While this may be manifested by LCD variations among Medicare Administrative Contractors (MACs), we note that variability is not a de facto sign of inappropriate local policy and may be appropriate.
- The health technology represents a substantial clinical advance and is likely to result in a significant improvement in patient health outcomes or positive impact on the Medicare program.
- When rapid diffusion of an item or service is anticipated the evidence may inadequately address questions regarding impact on the Medicare population, target subgroup

populations, practitioner or facility qualifications, etc., or on beneficiary health outcomes. Under these particularly complex circumstances, we may also require a comprehensive technology assessment, or convene a MEDCAC meeting to discern and evaluate those complexities and help inform our national decision.

2. Internally-Generated NCD Reconsideration Review

We may also internally open a reconsideration of any policy or of an entire NCD.

Generally, we internally open an NCD reconsideration because we have become aware of new evidence that could support a material change in coverage and we seek public comment on relevant questions.

E. Expedited Process to Remove an NCD Using Certain Criteria

We recognize the need to periodically review our policies and processes to ensure that we remain effective and efficient as well as open and transparent. We are aware that clinical science and technology evolve and that items and services that were once considered state-of-the-art or cutting edge may be replaced by more beneficial technologies or clinical paradigms. Therefore, we are announcing an administrative procedure to periodically review the inventory of NCDs that are older than 10 years since their most recent review and evaluate the continued need for those policies to remain active on a national scale. We are administratively simplifying the Medicare program by removing NCDs in circumstances described below. This process of removal would not result in an NCD as that term is defined in sections 1869(f) and 1862(l) of the Act because there would be no uniform national decision about whether or not the particular item or service would be covered under Title XVIII of the Act. Rather, the initial coverage decision under section 1862(a)(1)(A) of the Act for the particular item or service would be made by local contractors. We believe that allowing local contractor discretion in these cases better serves the needs of the Medicare program and its beneficiaries since we believe the future utilization for items and services within these policies will be limited.

This expedited procedure allows us to regularly identify and remove NCDs that no longer contain clinically pertinent and current information or that involve items or services that are used infrequently by beneficiaries. As the scientific community continues to pursue research in certain areas, the evidence base we previously reviewed may have evolved to support other policy conclusions. Alternatively, in some circumstances, removing an NCD has the effect of striking national noncoverage and may permit access to technologies that may be beneficial for some limited uses.

Under this process, we will periodically publish on our website, a list of NCDs proposed for removal along with our rationale for their proposed removal. We will solicit public comment for 30 calendar days. This will invite the public to comment on whether any or all of these NCDs should be removed or retained. In addition, we will ask the commenters to include a rationale to support their comments. We use the public comments to help inform our decision to do one of the following:

- Follow the proposal to remove the NCD.
- Retain the policy as an NCD.
- Formally reconsider the NCD and post a tracking sheet to that effect on the Coverage website.

We consider all the public comments when developing a final NCD list for removal. When the final NCD list for removal is posted to our Coverage website, we summarize the comments and briefly explain our rationale as to why a specific NCD remained active, was removed from active national status, or qualified for reconsideration. The final list will be effective upon posting it to the website.

Currently, an existing NCD must undergo a formal reconsideration process to be removed or amended and the process generally takes 9 to 12 months. We expect this new administrative procedure to reduce that time significantly. We believe that this streamlined

process is more efficient and helpful to the public because it instills confidence that national policies are being monitored to ensure health benefits for Medicare beneficiaries remain current.

We may consider an older NCD for removal if, among other things, any of the following circumstances apply:

- We believe that allowing local contractor discretion better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an “NCD” as defined in sections 1862(l) or 1869(f) of the Act.
- The benefit category determination is no longer consistent with a category in the Act.

V. CMS’ Evaluation of Requests for an NCD and Related Tasks

When we receive a request for an NCD, we review the submitted material to determine if it is a complete, formal written request. If it is not a complete, formal request it does not trigger the NCD statutory timeline because we do not have a clear basis upon which to act on the inquiry. In these instances, we notify the requester and explain our rationale, so the requester has the opportunity to provide missing information. As we explain elsewhere in this notice, many of the incomplete or informal inquiries we have received in the past did not ultimately result in a formal request.

Upon acceptance of a complete, formal, request, posting of the tracking sheet on our website facilitates the ability of interested individuals to participate in, and monitor, the progress of our review. This is a key element in making our NCD process more efficient, open, and accessible to the public.

We then undertake a formal evidence review to determine whether or not an unbiased interpretation of the available evidence base supports or refutes the requested coverage in whole or in part. We may also consider the need to obtain additional input through technology assessments from an outside entity and/or deliberation by the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). A formal review may result in an NCD, a noncoverage NCD, or an NCD with limitations. We also may determine that no NCD is required, permitting local Medicare contractors to make the initial determination under section 1862(a)(1) of the Act.

VI. Public Comment

We strive to conduct the NCD process in an open and transparent manner with thoughtful consideration of public comment. We have found that public commenters may cite published clinical evidence, contribute insight, and give us useful information. We are particularly interested in comments that include new evidence we have not reviewed for the proposed decision or in past considerations of the NCD. Comments should be timely and pertinent to the NCD. We respond in detail to the public comments on a proposed decision in the final decision memorandum.

While the statute affords an opportunity for public comment on the proposed decisions, we may also solicit public comment upon the initial opening of an NCD review announced via the tracking sheet. We use the initial public comments to inform our proposed decision and respond in detail to the public comments on a proposed decision when issuing the final decision memorandum.

Also, we may, at our discretion, open a proposed decision concurrently with the notice of opening an NCD. This occurs rarely when we determine it is efficient to reduce the time necessary to manage an unforeseen health related issue or program need that must be resolved quickly. We may also use our discretion, as we have publicly stated, in an attempt to expedite a

final NCD for requests that are accepted in the FDA CMS parallel review project (see the notice published on October 11, 2011 (76 FR 62808 through 62810)).

Public comments providing information on unpublished evidence, such as the results obtained by individual practitioners or patients, are less rigorous and therefore less useful for making a coverage determination.

Public comments that contain personally identifiable health information are either redacted or not made available to the public. Comments containing extensive personal health information may leave no substantive comment after redaction.

We prefer to receive comments electronically; as these are more efficiently reviewed, catalogued, and redacted for personally identifiable health information. If a commenter chooses to submit comments through more than one channel, duplicate submissions are treated as a single comment.

In general, we avoid opening and closing public comment periods on federal holidays or weekends. We may have limited ability to accommodate this goal, however, under tight statutory deadlines.

VII. Prioritizing Requests

In the event that we have a large volume of NCD requests for simultaneous review, we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries and staffing resources.

VIII. Time Frames

We strive to complete NCD-related activities in a timely and efficient manner, often before statutory deadlines. We prepare an annual Report to Congress that tracks our performance with respect to certain key steps in the process which is also posted on our website. The following steps and time frames are used for new NCDs and for reconsiderations of existing NCDs:

- Upon acceptance of a complete formal request or upon the opening of a CMS initiated review, we publish on our website a tracking sheet that provides public notice of the opening of the NCD process. We generally allow a 30-day public comment period on the NCD review topic announced via the tracking sheet. We use the initial public comments to inform a proposed decision. As stated above, at our discretion, we may announce a proposed decision concurrent with the notice of opening.

- A proposed decision is posted no later than 6 months after the posting of the tracking sheet, unless a technology assessment (TA) from an outside entity is commissioned, a clinical trial is requested, or a meeting of the MEDCAC is convened.

- In the event that a TA is commissioned from an outside entity or a MEDCAC meeting is held and a clinical trial is not requested, the proposed decision is posted no later than 9 months following the posting of the tracking sheet.

- Upon the posting of the proposed decision, there is a 30-day public comment period during which time the public is invited to comment on the substance of the proposed decision.

- A final NCD is posted on our website no later than 60 days following the close of the public comment period on the proposed decision.

- With publication of the final decision memorandum, the NCD is effective for claims with dates of service beginning with the effective date of the NCD. The memorandum contains, among other materials, the analysis and conclusions and also the NCD that becomes a part of the Medicare National Coverage Determination Manual (Pub.100-3) of the CMS Internet Only Manual. After enactment of section 1862(l) of the Act, the effective date for the NCD is the same date as the publication date of the final decision memorandum. Therefore, we have found it expedient and practical to include the NCD that is included in the Medicare National Coverage Determination manual in the final decision memoranda and to use that date as the effective date for Medicare coverage and payment purposes.

IX. Collection of Information Requirements

This document does not impose any new reporting, recordkeeping or third-party disclosure requirements. This document, however, does make reference to information associated with an existing information collection request. The information listed in section IV.B “What Constitutes a Complete, Formal Request for a National Coverage Determination or a Complete, Formal Request for Reconsideration” of this notice, was previously approved under OMB control number 0938–0776. We are currently seeking reinstatement of the OMB control number and the information collection requirements. We published the required 60-day notice on February 12, 2013 (78 FR 9927). The 60-day comment period ended April 15, 2013. We will announce the submission of the information collection request to OMB via the required 30-day notice.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare--Hospital Insurance Program; and No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: May 17, 2013

Marilyn Tavenner,
Administrator,
Centers for Medicare & Medicaid
Services.

Approved: May 17, 2013

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

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